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ARNOLD & PORTER

Holly Logue Prutz
Holly_Prutz@aporter.com

202.942.5243
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

September 8, 2003

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Application No. 09/606,977
Filed: June 28, 2000
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants
Applicant: Joseph R. BYRUM
Atty. Docket: 16517.144

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. an Appellant's Brief; and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicant requests that the following fee be charged to Deposit Account No. 50-2387 referencing docket number 16517.144:

$ 320.00 appeal brief fee

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicant does not believe any fees, other than the above fee ($320), are due in conjunction with this filing. However, if any additional fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the

Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387 referencing matter number 16517.144. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. Attorney No. 41,408)
Holly Logue Prutz (Reg. Attorney No. 47,755)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:		Conf. No.	6609
Joseph R. BYRUM		Art Unit:	1631
Appln. No.:	09/606,977	Examiner:	Marianne P. ALLEN
Filed:	June 28, 2000	Atty. Docket:	16517.144/38-21(15877)B
For:	**Nucleic Acid Molecules and Other Molecules Associated with Plants**		

APPELLANT'S BRIEF

Attn: Mail Stop Appeal Brief-Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the final rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on July 8, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-7 and 20-24 are pending. Claims 4, 20, and 24 were amended in the Amendment After Final Rejection filed on August 22, 2003 ("Amendment") to clarify the issues on appeal. Claims 2-3 and 6-7 stand finally rejected under 35 U.S.C. § 112, first paragraph. Claims 1-7 and 20-24 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Claims 20 and 24 stand finally rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 4, 20, and 23 stand finally rejected under 35 U.S.C. § 102(b). Applicant appeals all of the rejections of each of the claims.

4. Statue of Amendments

Applicant filed the Amendment adding a priority paragraph to the specification and amending claims 4, 20, and 24 to correct errors pointed out in the Final Office Action mailed April 8, 2003 (Paper No. 20) ("Final Action"). The Amendment is intended to clarify the issues with respect to the rejection of claims 20 and 24 under 35 U.S.C. § 112, first paragraph.

5. Summary of Invention

The invention is directed to nucleic acid molecules capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°, followed by a wash of 2.0 X SSC at 50° to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof. Specification at page 10, lines 5-8 and page 1516, line 1 to page 1517, line 16. The invention is also directed to a first nucleic acid molecule comprising a fragment nucleic acid sequence having from about 50 to about 100 nucleotide residues, wherein said fragment nucleic acid sequence exhibits complete complementarity to a second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof. Specification at page 10, lines 12-16 and page 15, line 18 to page 16, line 2.

6. Issues

The issues in this Appeal are:

(a) whether claims 2-3 and 6-7 are unpatentable under 35 U.S.C. § 112, first paragraph, for allegedly containing new matter;

(b) whether claims 1-7 and 20-24 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(c) whether claims 1-7 and 20-24 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility;

(d) whether claims 20 and 24 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description; and

(e) whether claims 1, 4, 20, and 23 are unpatentable under 35 U.S.C. § 102 for alleged anticipation.

7. Grouping of Claims

All of the claims at issue do not stand or fall together. Patentability of claims 2-3 and 6-7 is addressed in Section 9.B below. The separate patentability of claims 1-7 and 20-24 is addressed in Sections 9.C and 9.D below. The separate patentability of claims 20 and 24 is addressed in Section 9.E below. The separate patentability of claims 1, 4, 20, and 23 is addressed in Section 9.F below. A copy of the claims on appeal (prior to entry of the Amendment) is attached hereto as Appendix A. A copy of the claims on appeal (after entry of the Amendment) is attached hereto as Appendix B.

8. Preliminary Remarks

Applicant thanks the Examiner for withdrawing the rejection of claims 1 and 4 under 35 U.S.C. § 102(a) and for verifying that SEQ ID NO: 1 of the present application corresponds to SEQ ID NO: 1 of the provisional application.

Applicant also thanks the Examiner for pointing out that the specification does not contain a priority paragraph referencing U.S. Provisional Application No. 60/141,233. Applicant has amended the specification in the Amendment to include such a priority paragraph.

Applicant also notes that claims 4, 20, and 24 were amended in the Amendment. The amendments clarify the issues on appeal and do not present new matter. Further, it is submitted that the amendments do not raise new issues requiring further search and consideration by the Examiner.

9. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicant has met his part of the bargain – he has disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of a polymorphism in a population of soybean plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Applicant further asserts that claims 2-3 and 6-7 do not contain new matter.[1] All elements of the claims are described in the specification as filed. The introduction of the phrase

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[1] The Examiner placed this rejection under the heading "Claim Rejection - 35 U.S.C. § 101"; however, Applicant believes this was done in error and proceeds herein as if the rejection is a rejection under 35 U.S.C. § 112, first paragraph, new matter.

"further comprising" does not change the claims in such a manner that new matter is added. Moreover, it is well-established law that transitional phrases such as "having" and "comprising" are "open-ended and [do] not exclude additional, unrecited elements." *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 U.S.P.Q.2d 1608, 1613 (Fed. Cir. 1997); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 U.S.P.Q.2d 1398, 1410 (Fed. Cir. 1997) ("in the context of a cDNA having a sequence coding for human PI, the term 'having' permitted inclusion of other moieties"); M.P.E.P. § 2111.03. Because the claims as filed utilized such open-ended claim language, the premise of the Examiner's rejection that "further comprises" adds an additional element is incorrect, and the currently pending claims contain no new matter that was not present in Applicant's disclosure as filed.

Additionally, Applicant has provided an adequate description of the claimed nucleic acid molecules that demonstrates Applicant's possession of the claimed invention of claims 20 and 24. Applicant believes that the Examiner instead intended to reject claims 20 and 24 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Regardless, this rejection should be rendered moot by the claim amendments submitted in the Amendment.

Finally, claims 1, 4, 20, and 23 were erroneously rejected as anticipated by a reference that fails to teach the recited nucleic acid sequence. The Examiner improperly considered a non-identical chemical compound to anticipate the claims as drawn to SEQ ID NO: 1 or a complement thereof, despite the fact that the cited reference fails to teach the chemical composition of SEQ ID NO: 1 or a complement thereof. The Examiner has asserted an untenable interpretation of claims 1, 4, 20, and 23 that covers small fragments of the specifically claimed nucleic acid molecules, *i.e.*, molecules as short as a single nucleotide, and thus concludes that the claims are anticipated by the cited reference. However, the currently pending claims are directed to, for example, substantially purified nucleic acid molecules capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a

wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof. Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate the present claims.

Moreover, the Examiner based her rejection for anticipation not on what exists in the art or what the art teaches. Instead, the rejections of claims 1, 4, 20, and 23 are based on the Examiner's theory, unsupported by any evidence, that the prior art sequence might hybridize to fragments of the recited nucleic acids. Such clearly unsupported conjecture is simply not a proper basis for an anticipation rejection.

B. The Claims Are Supported by the Original Disclosure and Do Not Contain New Matter

Claims 2-3 and 6-7 were erroneously rejected as allegedly containing new matter. The Final Action asserts that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention." Final Action, page 2. Applicant respectfully points out that this rejection was erroneously placed under the heading "Claim Rejection – 35 U.S.C. § 101." Applicant will proceed, however, to respond to the 35 U.S.C. § 112, first paragraph, rejection which Applicant believes was intended.

The Examiner alleges that Applicant's claim amendment "to indicate that the nucleic acid molecule according to claim 1 'further comprises' an additional element" is new matter. Final Action, page 2. The Examiner contends that "[n]one of the portions of the specification pointed to provide support for these concepts." Final Action, page 2. The Examiner further alleges that the "originally filed claims and specification recite that the nucleic acid molecule according to claim 1 itself contains or is each of these elements" (emphasis added). Final Action, pages 2-3.

The term "comprising" is defined by Section 2111.03 of the M.P.E.P. as synonymous with "including," "containing," or "characterized by," and is inclusive of open-ended and does

not exclude additional, unrecited elements or method steps. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 U.S.P.Q.2d 1608, 1613 (Fed. Cir. 1997); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 U.S.P.Q.2d 1398, 1410 (Fed. Cir. 1997). Because claims 2-3 and 6-7 as originally filed were "comprising" claims, they did not exclude the possibility of further comprising the additional elements. Moreover, claims 2-3 and 6-7 depend from claim 1, which is directed to "a substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof". Contrary to the Examiner's assertion, the additional elements of each of these claims is not required to be found within SEQ ID NO: 1 or its complement, but rather may be found in a nucleic acid molecule that hybridizes to SEQ ID NO: 1 or its complement under the recited conditions.

The specification also describes these elements at page 1518, line 21 through page 1519, line 5; page 1520, line 1 through page 1522, line 2; and page 1526, lines 1-5. Thus, claims 2-3 and 6-7 as originally filed, along with the specification as originally filed, disclosed all of the elements of the claims.

In the previous Office Action mailed October 8, 2002, the Examiner rejected claims 2-4 and 6-7, alleging that the respective elements did not appear "to be contained within SEQ ID NO: 1." *See* Office Action mailed October 8, 2002, pages 4-5. The Examiner's rationale appeared to be that in the absence of the phrase "further comprising," the claims "must be interpreted to mean that the stated element is within the claimed SEQ ID NO: 1." *See* Office Action, page 5. While Applicant disagreed with the Examiner's rejection of the claims, Applicant amended claims 2, 3, and 7 to incorporate the phrase "further comprises" into the language of the claims in order to

clarify that, in fact, the recited elements were not required by the claims to be located within SEQ ID NO: 1.

It appears that the Examiner, in the Final Action, is claiming that the addition of the phrase "further comprising" constitutes new matter because "[t]he originally filed claims and specification recite that the nucleic acid molecule according to claim 1 itself contains or is each of these elements." Final Action, pages 2-3. Such an assertion is unfounded. Claim 1 as originally filed recites "a substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having a nucleic acid sequence... of SEQ ID NO: 1..." or complement thereof. Specification, page 1613, lines 2-5. Nowhere in claim 1 or its dependents was it ever recited that the additional elements must be or are contained within SEQ ID NO: 1. The Examiner's interpretation is incorrect and unsupported by the law and the language of the claims as originally filed.

Thus, the premise for the rejection of claims 2-3 and 6-7 under 35 U.S.C. § 112, first paragraph, for containing new matter is incorrect. Therefore, the rejection of claims 2-3 and 6-7 is improper and must be reversed.

C. The Claimed Nucleic Acids Have Legal Utility

Claims 1-7 and 20-24 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported by either a "specific, substantial and credible asserted utility or a well established utility." Final Action, page 3. The Final Action argues that, although the specification discloses that the nucleic acid molecules of the present invention encode proteins, are promoters, and are markers, "the specification does not fairly identify what SEQ ID NO: 1 is." Final Action, page 3.

Furthermore, rather than challenging the utilities disclosed throughout the specification for the claimed nucleic acid molecules, the Examiner requires Applicant to identify a classification for SEQ ID NO: 1. Final Action, page 4. Applicant knows of no requirement to further delineate SEQ ID NO: 1. If the Examiner is to maintain this rejection for failure of

Applicants to so delineate, then Applicant requests that the Examiner point to the legal authority giving the Examiner such authorization.

The Examiner's analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicant has asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use in comparative mapping. *See, e.g.*, specification at page 1563, line 8 through page 1571, line 5, and page 1560, line 1 through page 1563, line 7. Either of these

utilities described alone is enough to satisfy 35 U.S.C. § 101. Because Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and because he has done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicant has asserted that the claimed nucleic acid molecules[2] are themselves useful for the utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms and in comparative mapping. The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide or plant traits such as biochemical processes such as protein synthesis. Specification at page 1598, line 13 through page 1600, line 3. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[3] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[4] and use in monitoring gene expression. *See, e.g.,* specification at page 1571, line 13 through page 1575, line 20.

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[2] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicant is not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[3] *See, e.g.*, MPEP § 2107.01 at page 2100-32.

[4] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecule is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 1563, line 8 through page 1571, line 12. The Final Action argues that this utility, like all of the asserted utilities, is not specific or substantial, *see* Final Action, pages 4-5, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case, including this utility, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because the specification allegedly "does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism whatsoever. Thus, the specification leaves open the possibility that there may be no polymorphism to detect." Final Action, page 5. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself.

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the Examiner's assertions, this use is not using the claimed nucleic acid molecules to confirm a " 'real world' use." *See* Final Action, page 5. It is a **use** of the claimed nucleic acid molecules in a real world context.

Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acid molecules, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are in physical mapping or monitoring gene expression. Specification at page 1554, line 10 through page 1563, line 7 and at page 1571, line 13 through page 1575, line 17. The Examiner suggests that these uses are not legal utilities because "[f]urther experimentation would also be required for these uses," and thus "no meaningful information is provided." Final Action, page 5. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as rice, sorghum, or wheat.[6] Specification at page 1563, lines 1-7. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility

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[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicant to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicant has specifically disclosed that one use of the claimed nucleic acid molecules is in chromosome landing. Specification at page 1557, line 14 through page 1558, line 15. The Final Action denigrates that utility when it asserts "applicant does not appear to have identified any function for SEQ ID NO: 1". Final Action, page 4.

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action, pages 3-6. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

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[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, *e.g.,* to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, for example, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs and STCs is not merely an academic issue; the real world value of ESTs, for example, is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of these types of nucleic acid molecules is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107 at 2100-40.

Applicant has explicitly identified specific and substantial utilities, not only in the specification, but in Applicant's Response dated January 7, 2003, at page 5, lines 25 through 27. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

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[8] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

D. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1-7 and 20-24 were erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action, pages 6-7. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

E. The Specification Provides an Adequate Written Description of the Claimed Invention

Claims 20 and 24 were rejected for lack of written description. The Final Action asserts that the claimed invention contains "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Final Action, page 7. The Examiner alleges that claim 20 recites "comprises a nucleic acid molecule consisting of" and that "[t]he juxtaposition of open and closed language is confusing and 'comprising' is considered to control the scope of the claim." Final Action, page 7. The Examiner further alleges that claim 24 is dependent upon itself.

It appears that the Examiner meant to reject claims 20 and 24 under 35 U.S.C. § 112, second paragraph, for indefiniteness for alleged failure to particularly point out and distinctly claim the subject matter which the Applicant regards as his invention.

Regardless, Applicant respectfully disagrees with the rejection, however, claims 20 and 24 have been amended in the Amendment to facilitate prosecution. Applicant believes the rejection is rendered moot by the foregoing claim amendments. Reconsideration and withdrawal of this rejection are respectfully requested.

F. The Claimed DNA Constructs are Novel

The claimed nucleic acid molecules are novel over the prior art, yet were erroneously rejected under 35 U.S.C. §102 as allegedly anticipated by various references which fail to teach the entire recited nucleic acid sequence or a complement thereof. "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985).

Claims 1, 4, 20, and 23 were erroneously rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by NCBI Accession No. S42508, May 8, 1993, in the Final Action. According to the Final Action, NCBI Accession No. S42508 discloses a nucleotide sequence from *Zea mays* that "would hybridize under low stringency conditions of claim 1 to a second nucleic acid molecule having **a** nucleic acid sequence of SEQ ID NO: 1 or a complement." Final Action, page 8 (emphasis in original). This reference does not anticipate claims 1 and 2. For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*,

713 F.2d 760, 771 (Fed. Cir. 1983). NCBI Accession No. S42508 does not teach every element of the claimed invention.

(1) NCBI Accession Number S42508 Does Not Teach SEQ ID NO: 1 or a Complement Thereof

The Final Action maintains that NCBI Accession No. S42508 "would hybridize under the low stringency conditions of claim 1 to a second nucleic acid molecule having **a** nucleic acid sequence of SEQ ID NO: 1 or a complement." *(Emphasis in original).* Final Action, page 8. The Final Action further states that "[t]he use of the article "a" includes subsequences of SEQ ID NO: 1. *Id.* The Final Action also states that "[t]hese subsequences could be as small as a single nucleotide. *Id.*

NCBI Accession No. S42508 does not disclose SEQ ID NO: 1 or a complement thereof and, as such, cannot anticipate the claimed invention. The Examiner has applied an untenable interpretation of claim 1 to cover small fragments of the specifically claimed nucleic acid molecules, *i.e.*, molecules as short as a single nucleotide, and thus concludes that the claims are anticipated by the cited reference. This is not correct.

Nowhere in the present claims or specification does it state that SEQ ID NO: 1 or a complement of a nucleic acid molecule of the present invention may be as short as a single nucleotide. Nonetheless, the Final Action alleges that claims 1, 4, 20, and 23 "encompass a nucleic acid molecule having a single nucleotide in common with SEQ ID NO: 1 or its complement." Final Action, page 8. The Examiner has not read the claims in light of the specification, as required by law, but rather has attempted to substitute a different definition of "complement" that the Examiner prefers to the explicit definition in the specification. *See, e.g.*, specification at page 1516, line 1 through page 1517, line 12. As such, the Examiner has failed to demonstrate that the reference discloses SEQ ID NO: 1 or a complement thereof and thus the rejection of claims 1, 4, 20, and 23 over NCBI Accession No. S42508 must be withdrawn.

(2) NCBI Accession No. S42508 Does Not Teach a Nucleic Acid Molecule that Specifically Hybridizes to a Nucleic Acid Molecule Having a Sequence of SEQ ID NO: 1 or a Complement Thereof

As noted above, the Examiner alleges above that NCBI Accession No. S42508 "would hybridize under the low stringency conditions of clam 1 to a second nucleic acid molecule having **a** nucleic acid sequence of SEQ ID NO: 1 or a complement." *(Emphasis in original).* Final Action, page 8.

In the present application, pending claim 1, as amended, is directed to a substantially purified nucleic acid molecule capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof. The Examiner has applied an untenable interpretation of claim 1 to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, molecules as short as a single nucleotide, and thus concludes that the claim is anticipated by the cited reference. Final Action, page 8.

Moreover, no evidence, extrinsic or otherwise, has been presented by the Examiner in support of the proposition that NCBI Accession No. S42508 would specifically hybridize to a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof under the conditions specified by the claims. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicant to provide evidence that the nucleic acids are not identical and would not hybridize to the claimed nucleic acid molecules. This is not the law. And furthermore, because the Examiner has already admitted the nucleic acid sequence provided by NCBI Accession No. S42508 is <u>not</u> identical to SEQ ID NO: 1 or its complement (*see* Final Action, page 8), any such requirement to prove non-identity would seem to be moot. Therefore, the Examiner has failed to demonstrate that the reference discloses SEQ ID NO: 1 or a complement thereof, or that NCBI Accession No. S42508 would hybridize to SEQ ID NO: 1 or a

complement thereof, and thus the rejection of claims 1, 4, 20, and 23 over NCBI Accession No. S42508 must be withdrawn.

In view of the above, Applicant contends the rejection under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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Holly Logue Prutz
(Registration No. 47,755)
David R. Marsh
(Registration No. 41,408)

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)

ARNOLD & PORTER
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

APPENDIX A

Claims on appeal *prior to* entry of Amendment filed August 22, 2003

1. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a microsatellite sequence.

3. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a region having a single nucleotide polymorphism.

4. (Currently amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

5. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule further comprises a bacterial ORI site.

6. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a promoter or partial promoter region.

7. The substantially purified nucleic acid molecule according to claim 6, wherein said promoter region comprises a CAAT *cis* element and a TATA *cis* element and an additional *cis* element.

20. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule comprises a nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

21. A substantially purified first nucleic acid molecule comprising a fragment nucleic acid sequence having from about 50 to about 100 nucleotide residues; wherein said fragment nucleic acid sequence exhibits complete complementarity to a second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

22. The substantially purified first nucleic acid molecule according to claim 21, wherein said second nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

23. A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof.

24. The substantially purified nucleic acid molecule of claim 24, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 1 or complement thereof.

APPENDIX B

Claims on appeal *after* entry of Amendment filed August 22, 2003

1. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a microsatellite sequence.

3. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a region having a single nucleotide polymorphism.

4. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

5. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule further comprises a bacterial ORI site.

6. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule further comprises a promoter or partial promoter region.

7. The substantially purified nucleic acid molecule according to claim 6, wherein said promoter region comprises a CAAT *cis* element and a TATA *cis* element and an additional *cis* element.

20. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

21. A substantially purified first nucleic acid molecule comprising a fragment nucleic acid sequence having from about 50 to about 100 nucleotide residues; wherein said fragment nucleic acid sequence exhibits complete complementarity to a second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

22. The substantially purified first nucleic acid molecule according to claim 21, wherein said second nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

23. A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof.

24. The substantially purified nucleic acid molecule of claim 23, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 1 or complement thereof.